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Alternative Labour Pain Strategies Study

Submission date	Recruitment status	[ ] Prospectively registered
11/05/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/11/2010	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Project Reference Number 04/Q1606/70

Study information

Scientific Title

Acronym
ALPS

Study objectives
Does regular use of an established massage, breathing and visualization programme, from 36 weeks until birth, reduce maternal pain perception and
pharmacological analgesia in labour, compared to the effects of standard antenatal preparation and placebo?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Labour Pain Management

Interventions
Intervention: Massage group
The model is practised as follows: women attend a class at 35-37 weeks gestation with their chosen birth companion where the programme is introduced by the midwife/therapist. The importance of breathing awareness is emphasised and massage techniques are taught, synchronising them with breathing and visualisation. They are asked to practise this programme, with the help of a video, for at least 3 evenings a week, for about 30-45 minutes, until 39 weeks and then a combination of techniques every evening, until hospital admission for labour /induction. During labour in hospital, the intervention is supported by a self-selected group of midwives, who have successfully completed an accredited massage course and attended one information session on the needs and expectations of women in the placebo arm of the trial.

Placebo: Breathing/Visualisation
It is possible that the addition of an extra antenatal class specifically devoted to coping with pain

in labour will improve outcomes for women in the Massage group regardless of the use of massage. Therefore, this "placebo" group will be included as a second comparision to test whether additional social support in the massage group accounts for any observed difference. Couples receive an additional antenatal class devoted to coping with labour, which offers breathing techniques and visualisation, without the use of massage. They are asked to practise this programme, for at least 3 evenings a week, for about 30-45 minutes, until 39 weeks and then a combination of techniques every evening until hospital admission for labour/induction. During labour in hospital, the intervention is supported by a self-selected group of midwives, who have successfully completed an accredited massage course and attended one information session on the needs and expectations of women in the placebo arm of the trial.

Control: Usual care
The women and companions in this group will be asked to attend the usual antenatal preparation classes that are currently available at the trial site. At present there are 4 two-hour classes.

Blinding to such visibly different options will not be possible. However, information offered to women will focus on the use of complementary strategies for coping with pain, rather than focusing only on the use of massage and will not emphasise, or imply superiority of, one form of care over another. Instead current lack of knowledge about what helps women to cope with labour will be emphasised. The use of a Placebo group guards against the potentially confounding factor of additional information, social support and other non-pharmacological strategies for pain management.
A self-selected group of trained midwives will care for women in all three arms of the trial. This has been done to ensure that:
1. All participants are cared for by professionals who have achieved the same level of knowledge and competence
2. Midwives are adequately trained to undertake the intervention in a safe and effective manner, as and when necessary during labour
3. Midwives are adequately informed to support couples in the placebo group

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure will be self-reported labour pain. The visual analogue scale (VAS), a simple, widely used measure validated for use to assess overall labour pain, within 48 hours of birth will be given to all participating women to complete before transfer from labour care. The scale will be given to women during the second hour following birth when hormonal interactions that begin immediately following birth initiate maternal-infant contact and pain from perineal trauma is usually absent. This is ethically and physiologically preferable to use during labour, or to use of the more complex and time-consuming Magill Pain Questionnaire, that is also validated for such research.

Secondary outcome measures
Other methods of pain relief, obstetric interventions, birth outcomes, cord blood levels of stress hormones and women's satisfaction and sense of control.

Overall study start date
01/12/2004

Completion date
30/11/2005

Eligibility

Key inclusion criteria
Eligible women will include all pregnant women booked for care in the study period except for listed exclusions.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
90

Key exclusion criteria
1. Multiple pregnancy
2. Planned caesarean section
3. Medical problems that would preclude the use of massage techniques
4. Women who have previously used the massage programme
5. Women who have a strong preference for a particular form of pain relief
6. Women who do not speak fluent English
7. Women not intending to have a birth companion

Date of first enrolment
01/12/2004

Date of final enrolment
30/11/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Horton Maternity Hospital
Oxford
United Kingdom
OX16 9AL

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
Research & Development Department
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Sponsor type
Research council

Website
http://www.oxfordradcliffe.nhs.uk/

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Research council

Funder Name
Oxfordshire Health Services Research Committee (UK) (Application for Research Grant Reference - CM001)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2008		Yes	No